

COVER PAGE

Title: Innovative Tools to Expand HIV Self-Testing (I-TEST)

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Methods

Study aim

Study objective 1: To evaluate the effectiveness of youth participatory interventions on HIV testing and other key prevention services among at-risk, HIV-negative youth (14-24 years old)
Hypothesis: Youth participatory interventions will increase HIV testing and preventive service use

Study objective 2: To train youth-friendly health facilities on how provide youth-friendly health services to study participants referred to the facilities for additional sexually transmitted infections. For participants in the research study, data collection at the trained youth friendly health facilities will be supervised and performed by the Nigerian Institute of Medical Research. Youth friendly facilities will be trained using the World Health Organization's guidelines for youth-friendly clinics as well as the Nigerian Institute of Medical Research Protocol for administrative encounter data.

Study design

We conducted a pilot, quasi-experimental cohort study to evaluate five different models of service delivery across seven sites as part of the Innovative Tools to Expand Youth-friendly HIV Self-Testing (I-TEST) study, known locally as 4 Youth by Youth (4YBY). The trial was registered with ClinicalTrials.gov (NCT04070287).

Study procedure

Step 1: Participant enrollment. This will involve recruiting youth to participate in the pilot study. Participant recruitment strategies will include: social media, online, event- and venue based, participant referral, and walk-ins at study clinics. Participant enrollment will be completed by study team.

Step 2: Intervention implementation. Following participant recruitment and enrollment in the study. Study participants will be assigned to one of the 5 youth participatory interventions focused on expanding the uptake of HIV self-testing and key HIV prevention services. The pilot intervention implementation would occur for 6 months. NIMR will provide local training on HIV prevention to the five participatory interventions following their existing guidelines. The participatory interventions will be conducted in the locations of the five teams who emerged as winners from the innovation boot-camp.

- Intervention 1: This involves using “SMART Pack” a HIV self-testing kit to promote uptake of HIV self-testing among young people at community centers. The SMART pack is a re-branded and repackaged box for HIV self-testing kits. The intervention aims to promote distribution of HIVST kits through in institutions, vocational centers, and social media platforms. The intervention would also include a referral system, where participants provided with the HIV self-testing kits are provided with information with youth-friendly health facilities for uptake of testing for sexually transmitted infections. The intervention would be promoted using flyers at community events and schools. The flyers will provide information on the SMART pack and the location where the pack can

be obtained for individuals who are interested. For this pilot study, the intervention will be implemented in Yaba local government area in Lagos state.

- Intervention 2: The intervention involves using “Luv Box” a box that include personal hygiene products and HIV self-testing kit as strategy to promote uptake of HIV testing among young people. The Luv box is packaged in two colors: blue and pink. The LUVBox would be made available in supermarkets, on-line stores, mini-marts, pharmacies, neighborhood stores and markets, for easy accessibility in hard to reach areas. The intervention would be promoted using flyers at community events and schools. The flyers will provide information on the "Luv Box" and the location where the pack can be obtained for individuals who are interested. For this pilot study, the intervention will be implemented in Yaba in Lagos state.
- Intervention 3: The intervention involves using a program program called “Bili” that leverages community youth events such as football matches as a strategy to promote the uptake of HIV self-testing among young people. The HIV self-testing kits will be available for interested individuals at the community youth events. These events and information the HIV self-testing kits will be on flyers that would be promoted at community centers and schools. For this pilot study, the intervention will be implemented in Ngenevu/Bunker communities in Enugu state.
- Intervention 4: This intervention involve using “BeterDoc Safety kits” that includes HIV self-testing kit, location and phone number to the health centers in the community as a strategy to promote update of HIV self-testing among young people. The intervention would be promoted using flyers at community events and schools. The flyers will provide information on the "BeterDoc Safety Kits" and the location where the pack can be obtained for individuals who are interested. For this pilot study, the intervention will be implemented in Ibadan, Dugbe and Agbowo in Oyo state.
- Intervention 5: This intervention “IUNGO” involves using a program utilizes community vocational skills training centers to promote uptake of HIV self-testing among young people. The intervention would be promoted using flyers at community events and schools. The flyers will provide information on the HIV self-testing kits and the location where the pack can be obtained for individuals who are interested. For this pilot study, the intervention will be implemented in Akure South, Orita-Obele, Ipinsa, Ilara Mokin and Ijare in Ondo state.

Please note that these participatory interventions will only provide HIV self-testing kits and instructions of how to perform the test to participants. They will also provide referral coupons to youth friendly centers for sexually transmitted infections (STI) screening and treatment and preexposure prophylaxis (PrEP) awareness and referral for at-risk youth. The referral coupons are intended to provide study participants information on trained youth friendly centers that are involved with the research. The referral coupons give the study participants access to other sexually transmitted infections (STI) screening and treatment and pre-exposure prophylaxis (PrEP) awareness and referral at these health facilities. The intervention only provide participants with the HIV self-testing kits and then refer them to youth-friendly health facilities

for other testing services. The intervention does not involve monitoring HIV self-testing procedure, we will only be asking for self-reported HIV testing and other sexually transmitted diseases testing.

These youth friendly centers are currently working in partnership with our local partners, the Nigerian Institute of Medical Research to provide youth-friendly health services to young people in Nigeria (See Step 4). Trained staff at the centers will record administrative encounter data that will capture participants self-reporting of HIV self-testing. Trained staff will also perform STI screening and treatment as well as PrEP referral. All individuals diagnosed with HIV, will be promptly linked to care with the PEPFAR-supported clinical services provided by the Nigerian Institute of Medical Research. Please note the staff will be trained in Step 4 of this study.

Step 3: Baseline data collection. After allocation of participants into the intervention, study team will collect baseline data on HIV testing history, sexual behavior history, youth participation experience, and other related outcomes will be collected from recruited participants. Participants mobile phone numbers will also be collected as tracking information for follow-up and retention in a coupon format. The mobile phone numbers would be used to contact study participants through text messages and phone calls. These contacts would serve as reminders for participants to participate in follow-up data collection. The mobile phone service charge would be covered by the research. No other personal identifiers will be collected and no biological specimens will be collected at baseline. We will obtain informed consent before proceeding with any data collection.

Step 4: Health facilities training. For the purposes of this research study, the Nigerian Institute of Medical Research team would provide training to youth-friendly health centers currently working with the Nigerian Institute of Medical Research based on the World Health Organization guidebook for youth-friendly health services. The training would be to ensure that these health facilities are trained to provide youth friendly services to participants who be referred to receive STI screening, STI treatment and PrEP awareness and referral. Following the training, the NIMR research team would in charge of collecting data to record record participants HIV self-testing uptake as well as uptake of STI screening, STI treatment and PrEP awareness and referral.

Step 5: Follow up surveys: At 3- and 6-months post intervention implementation, study team will collect similar baseline data from study participants. The follow-up survey will assess HIV testing, sexual behavior history, youth participation experience and other related

Statistical analysis

1. We will assess the effect of participatory intervention on uptake of testing and prevention services using pre-post design. Specifically, baseline and follow-up survey data will be compared to assess trends in test uptake and linkage to prevention services. Bi-variate analyses will be conducted by comparing proportions of youth reporting a behavior between baseline and follow-up, using chi-square statistics. We will also analyze by intent to treat; participants who are lost or withdraw from the study will be considered failures in analysis of uptake of the particular intervention or service of interest.

2. We will assess factors associated with test uptake and linkage to related preventive services. This will be tested as a series of hypotheses using measures related to socio-demographic variables as well as key variables collected such as sexual behavior history and youth participation. A series of logistic regression analyses at baseline will identify significant correlates of HIV testing and linkage to prevention, focusing hypothesis testing on the measures collected. At completion of the study, the analyses can be extended to all data (baseline plus 3- and 6-month follow-ups for HIV-negative participants and baseline plus 3 month follow-ups for newly infected participants). The basic approach to analyzing longitudinal data will be generalized estimating equations (GEE), which accounts for correlation of the data (repeated observations for the same individuals) and both time-dependent and time independent Covariates.

Ethical consideration

Ethical approvals for the study were granted by the Saint Louis University and the NIMR Institutional Review Boards.